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August 16, 2023

Hon. Claire C. Cecchi, U.S.D.J.  
United States District Court for the District of New Jersey  
Martin Luther King, Jr. Bldg. & U.S. Courthouse  
Courtroom MLK 5B  
50 Walnut Street  
Newark, New Jersey 07101

**Re: Proton-Pump Inhibitor Products Liability Litigation (No. II)**  
**2:17-md-2789 (CCC) (LDW) (MDL 2789)**

Dear Judge Cecchi:

Pursuant to the Court's August 1, 2023 Order directing the parties to submit, by August 16, 2023, a joint letter listing all relevant briefing/submissions pertaining to Defendants' Motion for Summary Judgment on preemption grounds, Defendant's Motion for Summary Judgment on statute of limitations grounds in Rieder, PSC's Daubert Motion to Exclude Dr. Palase, PSC's Daubert Motion to Exclude Dr. Leonard-Segal, and PSC's Motion to Disqualify Dr. Leonard-Segal, attached please find the following:

1. Index regarding Defendants' Motion for Summary Judgment on preemption grounds attached hereto as Exhibit A;
2. Index regarding Defendants' Motion for Summary Judgment on statute of limitations grounds in Rieder, attached hereto as Exhibit B;
3. Index regarding PSC's Daubert Motion to Exclude Dr. Palese attached hereto as Exhibit C;
4. Index regarding PSC's Daubert Motion to Exclude Dr. Leonard-Segal attached hereto as Exhibit D;
5. Index regarding PSC's Motion to Disqualify Dr. Leonard-Segal attached hereto as Exhibit E.

In response to the Order's requirement that the parties submit a joint letter concerning the status of a proposed letter to the U.S. Food and Drug Administration as to Dr. Leonard-Segal's ability to appear before the Court in this matter, the parties advise that following the Court's June 22nd hearing, the parties had a telephonic meet and confer on July 3rd concerning a letter to the FDA regarding Dr. Leonard-Segal and agreed to evaluate a draft letter. The PSC sent a draft letter

to Takeda's counsel on August 8, 2023. Takeda responded on August 15, 2023. The PSC sent a further revised version on August 16, 2023, which Takeda is currently reviewing.

Respectfully submitted,

**MCCARTER & ENGLISH, LLP**

**/s/ Gregory J. Hindy**

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*Attorneys for Plaintiffs' Steering Committee*

cc: Ellen Reisman  
All counsel of record (via CM/ECF)

# Exhibit A

Date	Title	Docket nos.
10/7/2021	MOTION for Summary Judgment on preemption grounds by Takeda Responses due by 10/18/2021 attaching # 1 Statement of undisputed facts, # 2 Brief, # 3 Certification of M. Anderson, #4-38 Exhibits A - EE, # 39 Text of Proposed Order	Bales 71
10/7/2021	MOTION for Summary Judgment on Grounds that Plaintiffs' State Law Failure to Warn Claims are Preempted by AstraZeneca attaching # 1 Statement of Undisputed Material Facts, # 2 Brief, # 3 Certification of Gregory J. Hindy, #4-54 Exhibits A-VV, # 55 Text of Proposed Order, # 56 Certificate of Service	Bales 73 <sup>1</sup>
12/3/2021	MOTION for Leave to File Excess Pages - PSC's Motion for Leave to File Excess Pages for its Brief Opposing Defendants' Motion for Summary Judgment on Failure-to-Warn Preemption attaching # 1 Text of Proposed Order	MDL 727
12/3/2021	[PSC's] Response [Brief Opposing Defendants' Motions for Summary Judgement On Failure-to-Warn Preemption, Bales Dkt Nos. 69 and 71] attaching # 1 Plaintiffs' Response to AstraZeneca's Statement of Undisputed Material Facts in Support of its Motion for Summary Judgment on the Grounds that Plaintiffs' State Law Failure-to-Warn Claims are Preempted by Federal Law, # 2 Plaintiffs' Response to Takeda's Statement of Undisputed Material Facts in Support of its Motion for Summary Judgment on the Grounds that Plaintiffs' State Law Failure-to-Warn Claims are Preempted by Federal Law, # 3 Plaintiffs' Statement of Disputed Material Facts in Support of Their Opposition to Defendants' Motions for Summary Judgment on the Grounds that Plaintiffs' State Law Failure-to-Warn Claims are Preempted by Federal law, # 4 Certification of Paul J. Pennock in Opposition to Defendants' Motion for Summary Judgment on Failure-to-Warn Preemption	MDL 728
12/3/2021	Exhibits 1-145 of PSC's Brief Opposing Defendants' Motions for Summary Judgment on Failure-to-Warn Preemption	MDL 729
12/3/2021	Exhibits 146-245 of PSC's Brief Opposing Defendants' Motions for Summary Judgment on Failure-to-Warn Preemption	MDL 730
12/3/2021	Exhibits 246-346 of PSC's Brief Opposing Defendants' Motions for Summary Judgment on Failure-to-Warn Preemption	MDL 731
12/13/2021	RESPONSE to Motion filed by Takeda re 727 MOTION for Leave to File Excess Pages - PSC's Motion for Leave to File Excess Pages for its Brief Opposing Defendants' Motion for Summary Judgment on Failure-to-Warn Preemption	MDL 746

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<sup>1</sup> AstraZeneca has identified only the docket numbers in the *Bales* case for ease of reference, but has filed identical preemption briefing on the dockets for each of the six bellwether cases.

<b>Date</b>	<b>Title</b>	<b>Docket nos.</b>
1/28/2022	REPLY to Response to Motion filed by Takeda re 71 MOTION for Summary Judgment on preemption grounds attaching #1 Statement Response to Plaintiff's' Statement of Disputed Material Facts, # 2 Certification of V. Lodato, # 3 Exhibit A, # 4 Exhibit B, # 5 Exhibit v, # 6 Exhibit xi	Bales 100
1/28/2022	Takeda REPLY to Response to Motion filed by Takeda re 71 MOTION for Summary Judgment on preemption grounds reply ISO Motion for PSJ on Preemption Grounds attaching #1-17 Exhibits i-xix	Bales 101
1/28/2022	REPLY to Response to Motion filed by ASTRAZENECA LP, ASTRAZENECA PHARMACEUTICALS LP re 73 MOTION for Summary Judgment on Grounds that Plaintiffs' State Law Failure to Warn Claims are Preempted attaching # 1 Defendants' Response to Plaintiffs' Statement of Disputed Material Facts, # 2 Reply Certification of Gregory Hindy, # 3 Exhibit A	Bales 102
3/25/2022	Letter from Defendants AstraZeneca and Takeda Pharmaceuticals, Joint Letter Regarding Motions for Summary Judgment on the Grounds that Plaintiffs' State Law Failure-to-Warn Claims are Preempted by Federal Law	MDL 774 Bales 106
5/31/2022	BRIEF in Support filed by Takeda re 71 MOTION for Summary Judgment on preemption grounds [Proposed Findings of Fact and Conclusions of Law in Support of its Motion for Partial Summary Judgment on Preemption Grounds] attaching # 1 Brief in Support, # 2 Certification, # 3 Exhibit 5	Bales 109
5/31/2022	CERTIFICATION in Support filed by Takeda re 71 MOTION for Summary Judgment on preemption grounds attaching #1-5 Exhibits 1-4, 6	Bales 110
5/31/2022	BRIEF [filed by AstraZeneca] Supplemental in Further Support of Defendants' Motion for Summary Judgment on the Ground That Plaintiffs' State Law Failure-To-Warn Claims are Preempted by Federal Law attaching # 1 Findings of Fact & Conclusions of Law, # 2 Certification of Gregory Hindy, #3-8 Exhibits WW - BBB	Bales 111
5/31/2022	BRIEF Plaintiff Steering Committee's Supplemental Brief on Preemption Motions	MDL 790
5/31/2022	STATEMENT Plaintiff Steering Committee's Proposed Statement of Facts and Conclusions of Law by PLAINTIFFS' STEERING COMMITTEE	MDL 791
5/31/2022	Certification of Jeff Grand on behalf of PLAINTIFFS' STEERING COMMITTEE Re 791 Statement and Exhibits 347-382	MDL 792
6/8/2022	RESPONSE re 791 Statement [AstraZeneca's Response to Plaintiff Steering Committee's Proposed Statement of Facts and Conclusions of Law]	MDL 802

Date	Title	Docket nos.
6/8/2022	RESPONSE re 791 Statement [AstraZeneca's Response to Plaintiff Steering Committee's Proposed Statement of Facts and Conclusions of Law]	MDL 803
6/8/2022	STATEMENT Plaintiffs' Omnibus Response to the AstraZeneca and Takeda Defendants' Proposed Findings of Fact and Conclusions of Law by PLAINTIFFS' STEERING COMMITTEE attaching # 1 Certification of Jeffrey S. Grand	MDL 804
6/8/2022	MOTION to Seal [MDL Dkt nos. 790, 791, 792] by PLAINTIFFS' STEERING COMMITTEE attaching # 1 Text of Proposed Order	MDL 805
6/8/2022	RESPONSE [to the PSC's Proposed Statements of Fact] in Support filed by Takeda re 72 MOTION for Summary Judgment attaching # 1 Certification of S. Knutson	Bales 112
6/8/2022	RESPONSE in Support filed by Takeda re 72 MOTION for Summary Judgment attaching # 1 Exhibit 7	Bales 113
8/1/2022	REPORT & RECOMMENDATION of Special Master Ellen Reisman Regarding Defendants' Summary Judgment Motions as to Preemption of Failure to Warn Claims. Signed by Special Master Ellen Reisman on 8/1/2022 attaching #1 Exhibit 1 (Oral Argument, Apr. 5, 2022), # 2 Proposed Order	Bales 124
9/12/2022	OBJECTION to 124 Report and Recommendations of Special Master Ellen K. Reisman Regarding Defendants' Preemption Motions (Doc. 124) by Takeda attaching # 1 Certification of Andrea Glinka Przybysz, # 2 Exhibit A, # 3 Exhibit B	Bales 129
9/12/2022	[AstraZeneca's] BRIEF In Support of Defendants' Objections to the Special Master's Report and Recommendation Regarding Defendants' Preemption Motion	Bales 130
9/21/2022	BRIEF in Opposition to Defendants' Objections to the Special Masters Report and Recommendation Regarding Defendants' Preemption Motions	Bales 132
9/21/2022	MOTION to Seal Brief Opposing Defendants' Objections to the Special Masters Report and Recommendation Regarding Defendants' Preemption Motions by All Plaintiffs attaching #1 Text of Proposed Order	Bales 133
9/22/2022	Set Deadlines as to 133 MOTION to Seal Brief Opposing Defendants' Objections to the Special Masters Report and Recommendation Regarding Defendants' Preemption Motions. Motion set for 10/17/2022 before Judge Claire C. Cecchi. Unless otherwise directed by the Court, this motion will be decided on the papers and no appearances are required. Note that this is an automatically generated message from the Clerk's Office and does not supersede any previous or subsequent orders from the Court	NA



Date	Title	Docket nos.
10/4/2022	MOTION for Leave to File Takeda Defendants' Reply by Takeda attaching # 1 Brief Reply in Support of Objections to Report & Recommendation Denying Motion for Partial Summary Judgment on Preemption Grounds, # 2 Text of Proposed Order	Bales 135
1/17/2023	NOTICE by Takeda re 129 Objection to Report and Recommendations, Notice of Supplemental Authority [re <i>In re Zofran</i> ]	Bales 172
1/17/2023	NOTICE by ASTRAZENECA LP, ASTRAZENECA PHARMACEUTICALS LP re 130 Brief of Supplemental Authority [re <i>In re Zofran</i> ]	Bales 173
2/2/2023	MOTION for Leave to File a Supplemental Brief Opposing Defendants' Objections to the Special Master's Report and Recommendation Regarding Defendants' Preemption Motion by PLAINTIFFS' STEERING COMMITTEE attaching #1 Text of Proposed Order	MDL 903
2/2/2023	Exhibit to 903 Motion for Leave to File, PSC's Supplemental Brief Opposing Defendants' Objections to the Special Master's Report and Recommendation Regarding Defendants' Preemption Motion by PLAINTIFFS' STEERING COMMITTEE	MDL 904
2/2/2023	MOTION to Seal Supplemental Brief Opposing Defendants' Objections to the Special Master's Report and Recommendation Regarding Defendants' Preemption Motions by PLAINTIFFS' STEERING COMMITTEE and Attachment 1 Proposed Order	MDL 905
2/27/2023	RESPONSE in Opposition filed by ASTRAZENECA LP, ASTRAZENECA PHARMACEUTICALS LP, MERCK SHARP & DOHME CORP. re 903 MOTION for Leave to File a Supplemental Brief Opposing Defendants' Objections to the Special Master's Report and Recommendation Regarding Defendants' Preemption Motion	MDL 911
4/18/2023	ORDER GRANTING 135 Motion for Leave to File Reply In Support of Objections to Report & Recommendation Denying Motion for Partial Summary Judgment on Preemption Grounds	Bales 237
8/1/2023	MDL TEXT ORDER - Oral argument on the following motions shall proceed accordingly: exp...and preemption (December 8, 2023, at 10:00 a.m.). By August 16, 2023, the parties shall submit a joint letter listing all relevant briefing/submissions, including corresponding docket numbers, pertaining to the aforementioned motions. Fourteen days prior to each argument, each side shall submit a letter no longer than three pages summarizing their positions as to that motion....	MDL 944

# Exhibit B

Date	Title	Docket nos.
10/21/2021	Letter from Gregory Hindy, Esq. Regarding Filing of Amended Brief, Statement of Undisputed Material Facts, and Certification of Gregory J. Hindy re 29 MOTION for Summary Judgment on Statute of Limitation Grounds. (HINDY, GREGORY) (Entered: 10/21/2021)	Rieder 43
10/21/2021	AMENDED DOCUMENT by ASTRAZENECA LP, ASTRAZENECA PHARMACEUTICALS LP, MERCK & CO. INC.. Amendment to 29 MOTION for Summary Judgment on Statute of Limitation Grounds . Amended Memorandum of Law,. (Attachments: # 1 Amended Statement of Undisputed Material Facts, # 2 Amended Certification of GregoryJ. Hindy, Esq., # 3 Exhibit A, # 4 Exhibit B, # 5 Exhibit C, # 6 Exhibit D, # 7 Exhibit E, # 8 Exhibit F, # 9 Certificate of Service)(HINDY, GREGORY)	Rieder 44
1/10/2022	RESPONSE. (Attachments: # <a href="#">1</a> Plaintiff's Supplemental Statement of Material Facts in Opposition to Defendants' Amended Motion for Summary Judgment as to Plaintiff James Rieder on Statute of Limitations Grounds, # <a href="#">2</a> PSC's Response to Defendants' Amended Motion for Summary Judgment as to Plaintiff James Rieder on Statute of Limitations Grounds, # <a href="#">3</a> Plaintiff James Rieder's Exhibit List and Certification of Stephanie O'Connor, # <a href="#">4</a> Ex. 1, # <a href="#">5</a> Ex. 2, # <a href="#">6</a> Ex. 3, # <a href="#">7</a> Ex. 4, # <a href="#">8</a> Ex. 5, # <a href="#">9</a> Ex. 6, # <a href="#">10</a> Ex. 7, # <a href="#">11</a> Ex. 8, # <a href="#">12</a> Ex. 9, # <a href="#">13</a> Ex. 10, # <a href="#">14</a> Ex. 11, # <a href="#">15</a> Ex. 12, # <a href="#">16</a> Ex. 13, # <a href="#">17</a> Ex. 14, # <a href="#">18</a> Ex. 15, # <a href="#">19</a> Ex. 16, # <a href="#">20</a> Ex. 17)(SEEGER, CHRISTOPHER)	MDL 757
2/8/2022	REPLY BRIEF to Opposition to Motion filed by ASTRAZENECA LP, ASTRAZENECA PHARMACEUTICALS LP, MERCK & CO. INC. re 29 MOTION for Summary Judgment on Statute of Limitation Grounds and re 44 Amended Motion for Summary Judgment on Statute of Limitations Grounds (Attachments: # 1 In Response to Plaintiff's Supplemental Statement of Material Facts, # 2 Reply Certification of Gregory Hindy, # 3 Exhibit A, # 4 Exhibit B, # 5 Exhibit C)(HINDY, GREGORY)	Rieder 53
2/15/2022	MOTION for Leave to File Surreply in Opposition to Defendants' Amended Motion for Summary Judgment as to Plaintiff James Rieder on Statute of Limitation Grounds by PLAINTIFFS' STEERING COMMITTEE. (Attachments: # 1 PSC's Surreply to Defendants' Amended Motion for Summary Judgment as to Plaintiff James Rieder on Statute of Limitation Grounds, # 2 Text of Proposed Order)(SEEGER, CHRISTOPHER) (Entered: 02/15/2022)	MDL 762

Date	Title	Docket nos.
2/18/2022	Letter from Gregory Hindy in Opposition to re 762 MOTION for Leave to File Surreply in Opposition to Defendants' Amended Motion for Summary Judgment as to Plaintiff James Rieder on Statute of Limitation Grounds . (HINDY, GREGORY) (Entered: 02/18/2022)	MDL765
6/27/2022	REPORT & RECOMMENDATION of Special Master Ellen Reisman Regarding Defendants' Motion For Summary Judgment on Statute of Limitations Grounds. Signed by Special Master Ellen Reisman on 6/27/2022. (Attachments: # 1 Exhibit 1 (Oral Argument, Apr. 5, 2022), # 2 Proposed Order) (jl, ) (Entered: 06/27/2022)	Rieder 119
7/25/2022	BRIEF In Support of Objection to Report and Recommendation on Defendants Motion for Summary Judgment on Statute of Limitations Grounds Re: [ECF No. 44] [ECF No. 119] (Attachments: # 1 Text of Proposed Order)(HINDY, GREGORY) (Entered: 07/25/2022)	Rieder 156
8/8/2022	RESPONSE re 156 Brief. (AUTRY, JOSH) (Entered: 08/08/2022)  Document Title: PSC's RESPONSE TO DEFENDANTS' OBJECTION TO THE SPECIAL MASTER'S REPORT AND RECOMMENDATION ON THEIR MOTION FOR SUMMARY JUDGMENT ON STATUTE OF LIMITATIONS GROUNDS	Rieder 160
8/1/2023	MDL TEXT ORDER - Oral argument on the following motions shall proceed accordingly: exp...and preemption (December 8, 2023, at 10:00 a.m.). By August 16, 2023, the parties shall submit a joint letter listing all relevant briefing/submissions, including corresponding docket numbers, pertaining to the aforementioned motions. Fourteen days prior to each argument, each side shall submit a letter no longer than three pages summarizing their positions as to that motion....	MDL 944

# Exhibit C

Date	Title	Docket nos.
10/15/2021	PSC's Notice of Plaintiffs' Omnibus Daubert Motion to Exclude Defense Experts (Attachments: # 1 Text of Proposed Order)	MDL 702
10/15/2021	BRIEF in Support filed by [PSC] re ... PSC's Notice of Plaintiffs' Omnibus Daubert Motion to Exclude Defense Experts (Attachments: #1-29 Exhibits 1-29)	MDL 703
12/10/2021	RESPONSE in Opposition filed by ASTRAZENECA LP, ASTRAZENECA PHARMACEUTICALS LP, MERCK & CO. D/B/A MERCK SHARP & DOHME CORP., MERCK SHARP & DOHME CORP. re ... PSC's Notice of Plaintiffs' Omnibus Daubert Motion to Exclude Defense Experts (Attachments: # 1 Certification of Gregory Hindy, # 2-26 Exhibits A-Y, # 27 Certificate of Service)	MDL 734
1/6/2022	[PSC's] MOTION for Leave to File Excess Pages ... for its Reply Brief in Support of Plaintiffs' Omnibus Daubert Motion to Exclude Certain Defense Experts (Attachments: # 1 Text of Proposed Order)	MDL 751
1/6/2022	[PSC's] REPLY BRIEF to Opposition to Motion filed by [PSC] re ... PSC's Notice of Plaintiffs' Omnibus Daubert Motion to Exclude Defense Experts – PSC's Reply Memorandum in Support of Plaintiffs' Omnibus Daubert Motion to Exclude Certain Defense Experts (Attachments: # 1-3 Exhibits R1-R3)	MDL 752
7/5/2022	REPORT & RECOMMENDATION of Special Master Ellen K. Reisman regarding Daubert Motions	MDL 811
7/27/2022	BRIEF In Support of Defendants' Objections to the Special Master's Report and Recommendations Regarding Daubert Motions [ECF No. 811] & [ECF No. 823] (Attachments: # 1 Certification of Gregory Hindy, # 2-7 Exhibits A-F)	MDL 824
8/10/2022	[PSC's] RESPONSE re 824 Brief [Defendants' Objections to the Special Master's Report and Recommendations Regarding Daubert Motions]	MDL 830
8/10/2022	[PSC's] MOTION to Seal the Briefs in Opposition to Defendants' Objections to the Special Master's Report & Recommendations regarding Daubert Motions (Attachments: # 1 Text of Proposed Order)	MDL 833
8/1/2023	MDL TEXT ORDER - Oral argument on the following motions shall proceed accordingly: experts Palese and Leonard-Segal (October 20, 2023, at 10:00 a.m.).... By August 16, 2023, the parties shall submit a joint letter listing all relevant briefing/submissions, including corresponding docket numbers, pertaining to the aforementioned motions. Fourteen days prior to	MDL 944

Date	Title	Docket nos.
	each argument, each side shall submit a letter no longer than three pages summarizing their positions as to that motion....	

# Exhibit D



## PSC's Motion to Exclude Leonard-Segal Pursuant to Daubert and Rule 702 Pleadings

Date	Title	Docket nos.
10/15/2021	[PSC's] MOTION in Limine Motion to Disqualify Takeda Defense Expert Dr. Andrea Leonard-Segal (Attachments: # 1 Text of Proposed Order)	MDL 702
10/15/2021	BRIEF in Support filed by PLAINTIFFS' STEERING COMMITTEE re 702 MOTION in Limine -PSC's Notice of Plaintiffs' Omnibus Daubert Motion to Exclude Defense Experts (Attachments: # 1-29 Exhibits 1-29)	MDL 703
12/10/2021	BRIEF [filed by Takeda] in opposition to Plaintiff's motion to exclude expert testimony of Dr. Andrea Leonard-Segal (Attachments: # 1 Certification of V. Lodato, # 2 Exhibit A)	Bales 88
1/6/2022	[PSC's] REPLY BRIEF to Opposition to Motion filed by PLAINTIFFS' STEERING COMMITTEE re 702 MOTION in Limine -PSC's Notice of Plaintiffs' Omnibus Daubert Motion to Exclude Defense Experts – PSC's Reply Memorandum in Support of Plaintiffs' Motion to Exclude Dr. Andrea Leonard-Segal Pursuant to Daubert and Rule 702	MDL 750

# Exhibit E

## PSC's Motion to Disqualify Dr. Leonard-Segal

<b>Date</b>	<b>Title</b>	<b>Docket nos.</b>
10/15/2021	[PSC's] MOTION in Limine Motion to Disqualify Takeda Defense Expert Dr. Andrea Leonard-Segal by [PSC]	MDL 700
10/15/2021	BRIEF in Support filed by [PSC] re 700 MOTION in Limine Motion to Disqualify Takeda Defense Expert Dr. Andrea Leonard-Segal (Attachments: # 1-33 Exhibits 1-33, #34 Proposed Order)	MDL 701
12/10/2021	[Takeda's] BRIEF in Opposition to Plaintiff's Motion to Disqualify Takeda Regulatory Expert Dr. Andrea Leonard-Segal (Attachments: # 1 Certification of V. Lodato, # 2-3 Exhibits A-B).	Bales 89
1/06/2022	REPLY BRIEF to Opposition to Motion filed by [PSC] re 700 MOTION in Limine Motion to Disqualify Takeda Defense Expert Dr. Andrea Leonard-Segal (Attachments: # 1 Certification of Stephanie O'Connor, # 2-18 Exhibits 34-50).	MDL 753
6/17/2022	REPORT & RECOMMENDATION of Special Master Ellen Reisman Regarding Plaintiff Bales's Motion to Disqualify Dr. Andrea Leonard-Segal (Attachments: # 1 Oral Argument, Apr. 4, 2022, # 2 Proposed Order)	Bales 114
7/8/2022	Defendants' Objections to the Report and Recommendation of Special Master Ellen Reisman re: filed by Takeda	Bales 117
7/22/2022	[PSC'S] Brief in Opposition to Defendants' Objections to the Report and Recommendation of Special Master Ellen Reisman Regarding Plaintiff Bales' Motion to Disqualify Takeda Defense Expert Dr. Andrea Leonard-Segal (Attachments: # 1-6 Exhibits 1-6, # 7 Exhibit 18, # 8 Exhibit 49, # 9 Exhibit 50)	MDL 818